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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,145	12/22/2006	Shyam S. Mohapatra	USF-T192XC1	1541

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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
07/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/544,145	MOHAPATRA, SHYAM S.	
	Examiner	Art Unit	
	Scott D. Long	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-13 and 16-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-13 and 16-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/6/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 9, 14-15, and 23 are cancelled. Claims 3-4, 7-8, 12-13, 16, and 19-22 are amended. Claims 1-8, 10-13, and 16-22 are under current examination.

Oath/Declaration

The new oath or declaration, having the signatures of all inventors, received on 22 December 2006 is in compliance with 37 CFR 1.63.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 11 April 2007 consisting of 7 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit as a 371 of PCT/US04/04262 (filed 02/13/2004) which claims benefit of 60/319,946 (filed 02/14/2003) and claims benefit of 60/319,956 (filed 02/19/2003). The instant application has been granted the benefit date, 02/14/2003, from the application 60/319,946.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

WRITTEN DESCRIPTION

Claims 1-8, 10-13, and 16-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement;* (Federal Register/Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claims 1, 5, 10, 17, and 21 are broadly drawn, such that they apply to a genus of particles comprising chitosan derivatives. However, the working examples provided in

the instant application only demonstrate individual species of particles, specifically comprising chitosan.

The instant specification indicates, "derivatives of chitin, or poly-N-aceryl-D-glucosamine (including all polyglucosamine and oligomers of glucosamine materials of different molecular weights), in which the greater proportion of the N-acetyl groups have been removed through hydrolysis." (page 10, lines 11-14). The specification further states, "'chitosan derivatives are intended to include ester, ether or other derivatives formed by bonding of acyl and/or alkyl groups with OH groups, but not the NH_2 groups, of chitosan. Examples are 0-alkyl ethers of chitosan and 0-acyl esters of chitosan. Modified chitosans, particularly those conjugated to polyethylene glycol, are included in this definition." (page 10, lines 21-25). The specification also describes, "chitosan (or chitosan derivative or salt) used preferably has a molecular weight of 4,000 Dalton or more, preferably in the range 25,000 to 2,000,000 Dalton, and most preferably about 50,000 to 300,000 Dalton." (page 11, lines 3-4).

Despite the defining the genus of chitosan derivatives by listing potential linkages and sizes recited in the specification and cited above, the instant application only has working examples of particles that comprise chitosan.

See MPEP § 2163, which states "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, ***even when accompanied by a method of obtaining the claimed sequence."***

The Revised Interim Guideline for Examination of Patent Applications under 35 USC § 112, p1 "Written Description" Requirement (Federal Register/ Vol 66. No 4, Friday January 5, 2001) states "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (column 2, page 71436, emphasis added).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "APPLICANT MUST CONVEY WITH REASONABLE CLARITY TO THOSE SKILLED IN THE ART THAT, AS OF THE FILING DATE SOUGHT, HE OR SHE WAS IN POSSESSION OF THE INVENTION. THE INVENTION IS, FOR PURPOSES OF THE 'WRITTEN DESCRIPTION' INQUIRY, *WHATEVER IS NOW CLAIMED*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize the [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Considering the potentially large numbers of molecules encompassed by these claims, the disclosure is not sufficient to show that a skilled artisan would recognize that

the applicant was in possession of the claimed invention (genus) commensurate to its scope at the time the application was filed.

SCOPE OF ENABLEMENT

Claims 10-13, and 16-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for delivery of a polynucleotide to a host, does not reasonably provide enablement for sustained *in vivo* gene delivery for the purpose of treating a disease state in a human host. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some 'experimentation.'" Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the

breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

SCOPE OF THE INVENTION

The breadth of the claims encompasses a method for regulating cytokines in a human subject suffering from asthma. As discussed supra, the specification fails to describe successful modulation of cytokines in asthmatic human subjects and would require undue experimentation to discover these embodiments. The specification only discloses and provides guidance for gene delivery using particles comprising chitosan.

GUIDANCE & WORKING EXAMPLES

The specification does not provide guidance for or a working example for modulating cytokines in an asthmatic human subject. The absence of working examples directed to modulating cytokines in an asthmatic human subject necessitates further experimentation. Therefore, the specification does not provide sufficient guidance on how to make and use particles of the instant invention for human gene therapy wherein cytokines are modulated in asthmatic patients.

STATE OF THE ART & QUANTITY OF EXPERIMENTATION

The nature of the invention being gene therapy, the state of the prior art is not well developed and is highly unpredictable. Verma et al (Nat. 1997 Sep; 389:239-242) states that out of the more than 200 clinical trials currently underway, no single outcome

can be pointed to as a success story (page 239, col. 1). For instance, numerous factors complicate the gene therapy art which have not been shown to be overcome by routine experimentation. Eck et al. (Phar Basis Ther 1995; 77-101) explains, the fate of the DNA vector itself (volume of distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. These factors differ dramatically based on the vector used, the protein being produced, and the disease being treated. (paragraph bridging pages 81-82) Verma et al. states that one major obstacle to success has been the inability to deliver genes efficiently and obtain sustained expression (see Verma et al., page 239, col. 3).

In fact, the state of the art teaches that gene therapy is not a highly successful technique or has highly variable results. Consequently, there is ample reason to conclude that there would be a high degree of unpredictability in a mammalian embodiment of the instant invention.

CONCLUSION

Therefore, it is concluded that based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working

examples provided, and the breadth of the claims that it would require undue experimentation to practice the invention.

In conclusion, given the breadth of the claims and the limited scope of the specification, an undue quantity of experimentation is require to make and use the invention beyond the scope of gene delivery using particles comprising chitosan.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-5, 7-8, 10, 12-13, 16-18, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Truong et al (WO99/36089, published 22 July 1999).

Claim 1 is directed to a particle comprising chitosan, or a derivative thereof; and a polynucleotide. Truong et al. teach a nanosphere comprising nucleic acids and chitosan (page 3, lines 8-13).

Claim 3 is directed to the particle of claims 1, wherein said polynucleotide encodes a cytokine. Truong et al. teach a nanosphere wherein at least a portion of the nucleic acid encodes a cytokine (page 20, line 14).

Claim 4 is directed to the particle of claim 1, wherein said polynucleotide encodes interferon gamma. Truong et al. teach the nanospheres comprising interferon gamma. The nucleic acids that encode a cytokine (claim 3) would intrinsically encode those cytokines taught by Truong et al, including, interferon gamma.

Claim 5 is directed to a composition comprising a particle and a pharmaceutically acceptable carrier, wherein said particle comprises chitosan, or a derivative thereof, and a polynucleotide. Truong et al. teach nanospheres are pharmaceutical formulations (page 6, lines 23-24).

Claim 7 is directed to the composition of claim 5, wherein said polynucleotide encodes a cytokine. Truong et al. teach a nanosphere wherein at least a portion of the nucleic acid encodes a cytokine (page 20, line 14). Truong et al. teach nanospheres are pharmaceutical formulation (page 6, lines 23-24).

Claim 8 is directed to the composition of claim 5, wherein said polynucleotide encodes interferon gamma. Truong et al. teach the nanospheres comprising interferon gamma. The nucleic acids that encode a cytokine (claim 8) would intrinsically encode those cytokines taught by Truong et al, including, interferon gamma.

Claim 10 is directed to a method for delivery and expression of a polynucleotide within host, said method comprising administering a particle to the host, wherein the particle comprises chitosan, or a derivative thereof, and a polynucleotide. Truong et al. teach "delivery of genes...to mammals...[and] expression of [genes]" using their particles. (abstract)

Claim 12 is directed to the method of claim 10, wherein the polynucleotide encodes a cytokine. Truong et al. teach a nanosphere wherein at least a portion of the nucleic acid encodes a cytokine (page 20, line 14).

Claim 13 is directed to the method of claim 10, wherein the polynucleotide encodes interferon gamma. Truong et al. teach the nanospheres comprising interferon gamma. The nucleic acids that encode a cytokine (claim12) would intrinsically encode those cytokines taught by Truong et al, including, interferon gamma.

Claim 16 is directed to the method of claim 10, wherein the particle is administered within a composition comprising a pharmaceutically acceptable carrier. Truong et al. teach nanospheres are pharmaceutical formulation (page 6, lines 23-24).

Claim 17 is directed to a method for enhancing interferon-gamma expression to regulate the production of cytokines secreted by T-helper type 2 (Th2) cells, said method comprising administering an effective amount of a particle to a subject, wherein the particle comprises chitosan, or a derivative thereof, and a polynucleotide encoding interferon-gamma. Truong et al. teach enhanced immune response (abstract) after administration of their compositions and "the cytokines either enhance presentation to antigenst to T cells or provide additional co-stimulatory for T cell activation (page 2,

lines 13-14). Truong et al. teach the nanospheres comprising interferon gamma. The nucleic acids that encode a cytokine (claim12) would intrinsically encode those cytokines taught by Truong et al, including, interferon gamma.

Claim 18 is directed to the method of claim 17, wherein the subject is human. Truong et al. teach that their compositions could be used to treat humans (page 15, line 16).

Claim 20 is directed to the method of claim 17, wherein the particle is administered to the respiratory tract of the subject. Truong et al. teach administration of the compositions to lung (page 11, line 16).

Claim 21 is directed to a method for producing a particle comprising a complex of chitosan, or a derivative thereof and a polynucleotide, said method comprising mixing the polynucleotide and the chitosan or chitosan derivative, to form the particle. Truong et al. teach creating the particles through a process of mixing (page 7, lines 6).

Accordingly, Truong et al. anticipated the instant claims.

Claims 1-8, 10-13, and 16-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al (US2002/0151009, published 17 October 2002).

Claim 1 is directed to a particle comprising chitosan, or a derivative thereof; and a polynucleotide. Ni et al. teach formulations comprising nucleic acids and chitosan (page 113, parag. 1032).

Claim 2 is directed to the nanoparticle of claim 1, wherein said particle further comprises a lipid, and wherein said particle comprises a complex of said chitosan, said polynucleotide, and said lipid. Ni et al. teach formulations comprising nucleic acids and chitosan and combinations and mixtures of other materials (page 113, parag. 1032). Ni further teaches that chitosan and other materials can be modified to obtain desired drug release profile (page 113, parag. 1032). Ni et al. also teach formulations comprising nucleic acids and biodegradable polymer (chitosan) may also include release-rate modification agents and/or pore-forming agents...including fatty acids (lipids) (page 113, parag.1034). Ni et al. teach a variety of liposomes (page 56, parags. 0537-0538).

Claim 3 is directed to the particle of claims 1, wherein said polynucleotide encodes a cytokine. Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272).

Claim 4 is directed to the particle of claim 1, wherein said polynucleotide encodes interferon gamma. Ni et al. teach interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272).

Claim 5 is directed to a composition comprising a particle and a pharmaceutically acceptable carrier, wherein said particle comprises chitosan, or a derivative thereof, and

a polynucleotide. Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407).

Claim 6 is directed to the composition of claim 5, wherein said particle further comprises a lipid, and wherein said particle comprises a complex of said chitosan, said polynucleotide, and said lipid. Ni et al. teach formulations comprising nucleic acids and chitosan and combinations and mixtures of other materials (page 113, parag. 1032). Ni further teaches that chitosan and other materials can be modified to obtain desired drug release profile (page 113, parag. 1032). Ni et al. also teach formulations comprising nucleic acids and biodegradable polymer (chitosan) may also include release-rate modification agents and/or pore-forming agents...including fatty acids (lipids) (page 113, parag.1034). Ni et al. teach a variety of liposomes (page 56, parags. 0537-0538). Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407).

Claim 7 is directed to the composition of claim 5, wherein said polynucleotide encodes a cytokine. Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272). Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407).

Claim 8 is directed to the composition of claim 5, wherein said polynucleotide encodes interferon gamma. Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al.

teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272). Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407).

Claim 10 is directed to a method for delivery and expression of a polynucleotide within host, said method comprising administering a particle to the host, wherein the particle comprises chitosan, or a derivative thereof, and a polynucleotide. Ni et al. teach, "Various delivery systems are known and can be used to administer a compound of the invention, e.g., encapsulation in liposomes, microparticles, microcapsules, recombinant cells capable of expressing the compound," (page 43, parag.0411).

Claim 11 is directed to the method of claim 10, wherein the particle further comprises a lipid, and wherein the particle is a complex of the chitosan, polynucleotide, and lipid. Ni et al. teach, "Various delivery systems are known and can be used to administer a compound of the invention, e.g., encapsulation in liposomes, microparticles, microcapsules, recombinant cells capable of expressing the compound," (page 43, parag.0411). Ni et al. teach formulations comprising nucleic acids and chitosan and combinations and mixtures of other materials (page 113, parag. 1032). Ni further teaches that chitosan and other materials can be modified to obtain desired drug release profile (page 113, parag. 1032). Ni et al. also teach formulations comprising nucleic acids and biodegradable polymer (chitosan) may also include release-rate modification agents and/or pore-forming agents...including fatty acids (lipids) (page 113,

parag.1034). Ni et al. teach a variety of liposomes (page 56, parags. 0537-0538). Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407).

Claim 12 is directed to the method of claim 10, wherein the polynucleotide encodes a cytokine. Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272).

Claim 13 is directed to the method of claim 10, wherein the polynucleotide encodes interferon gamma. Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272).

Claim 16 is directed to the method of claim 10, wherein the particle is administered within a composition comprising a pharmaceutically acceptable carrier. Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407).

Claim 17 is directed to a method for enhancing interferon-gamma expression to regulate the production of cytokines secreted by T-helper type 2 (Th2) cells, said method comprising administering an effective amount of a particle to a subject, wherein the particle comprises chitosan, or a derivative thereof, and a polynucleotide encoding interferon-gamma. Ni et al. teach polynucleotides of the present invention may be

useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272). Ni et al. also teach "administration of polynucleotides...of the present invention...[modulate] proliferation, differentiation, or chemotaxis of T-cells" (page 59-60, parag.0580).

Claim 18 is directed to the method of claim 17, wherein the subject is human. Vi et al. teach that their compositions could be used to treat humans (page 58, parag. 0563).

Claim 19 is directed to the method of claim 17, wherein the subject is suffering from asthma. Vi et al. teach, "compositions of the invention may be used as agents for immunological disorders including...asthma." (page 7, parag.0086).

Claim 20 is directed to the method of claim 17, wherein the particle is administered to the respiratory tract of the subject. Vi et al. teach aerosol administration of the compositions (page 58, parag. 0561).

Claim 21 is directed to a method for producing a particle comprising a complex of chitosan, or a derivative thereof and a polynucleotide, said method comprising mixing the polynucleotide and the chitosan or chitosan derivative, to form the particle. Ni et al. teach formulations comprising nucleic acids and chitosan and combinations and mixtures of other materials (page 113, parag. 1032). Vi et al. teach creating the particles through a process of mixing (page 44, parag.0418).

Claim 22 is directed to the method of claim 21, wherein said method further comprises mixing a lipid with polynucleotide and the chitosan or chitosan derivative, wherein the particle comprises a complex of polynucleotide, chitosan or chitosan derivative, and the lipid. Ni et al. teach, "Various delivery systems are known and can be used to administer a compound of the invention, e.g., encapsulation in liposomes, microparticles, microcapsules, recombinant cells capable of expressing the compound," (page 43, parag.0411). Ni et al. teach formulations comprising nucleic acids and chitosan and combinations and mixtures of other materials (page 113, parag. 1032). Ni further teaches that chitosan and other materials can be modified to obtain desired drug release profile (page 113, parag. 1032). Ni et al. also teach formulations comprising nucleic acids and biodegradable polymer (chitosan) may also include release-rate modification agents and/or pore-forming agents...including fatty acids (lipids) (page 113, parag.1034). Ni et al. teach a variety of liposomes (page 56, parags. 0537-0538). Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407). Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272).

Accordingly, Vi et al. anticipated the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-13, 16-18 and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 9-10, 13, and 15-18 of U.S. Pre-grant Publication No. US2005/266093. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims are directed to particles and methods comprising nucleic acids encoding gamma interferon, chitosan, and lipids, administered to the respiratory tract are essentially the same as claims to the cited application.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
Patent Examiner
Art Unit 1633

/Janet L. Epps-Ford/
Primary Examiner
Art Unit 1633